REMARKS

As requested, Applicants have amended the priority claim in the specification to recite the issuance of U.S. Patent No. 6,777,000.

In response to the Office Action, Applicants have amended some of the application claims, as listed above. Support for the amendments to independent claims 1, 42, 53, and 111 have been amended to recite that the compositions are in the form of a powder, and that the powder comprises a plurality of microparticles and/or microspheres having a particle size suitable to permit the microparticles or microspheres to pass through a sieve having an opening size of about 250 μM in diameter. Support for these amendments can be found in the specification at page 21, and in original claims 4, 5, 47, 54, 63, and 64.

In view of the amendments above, claims 3-5, 43, 47, 54, 63, and 64 have been canceled, without prejudice to or disclaimer thereof.

The misspelling of "phosphate" in claim 91 has been corrected.

The rejections of claims 65 and 106-110 under 35 U.S.C. § 112, 2nd paragraph have been overcome by amending the dependencies of those claims to recite corrected dependencies that reflect the original intent of the claims.

The rejection of claim 111 under 35 U.S.C. § 112, 2nd paragraph has been overcome by revising the order of the words relating to the mucosal surfaces so as to overcome any question of antecedent basis. This amendment does not narrow the claim.

REJECTIONS OF CLAIMS 32 AND 33 UNDER 35 U.S.C. § 112, 2ND PARAGRAPH

The Examiner rejected claims 32 and 33 for alleged indefiniteness, "because it is unclear if the solid gel inducing composition phase must be distinct from some other component, or

whether it is distinct simply because it is solid. It is also unclear what is intended by 'a solid mixture on the molecular level.' It is unclear what 'on the molecular level' adds to the claim. If something is solid, it is solid at all levels. Does Applicant intend a mixture of individual molecules, rather than *e.g.* crystals or other particles?"

Applicants have amended claim 32 (in view of the specification support on page 26) to clarify that in the claimed embodiments, the polysaccharides and the physiologically active agents form a solid mixed composition phase wherein the agent and the polysaccharide are "intimately mixed on a molecular level" (as contrasted to a physical mixture of distinct pure particles of agent and polysaccharide). The one or more solid gel inducing compositions are present as distinct solid phases (*i.e.* the particles of the solid gel inducing composition particles are physically distinct from the particles of the solid mixed composition phase.

As to the meaning of "intimately mixed on a molecular level," Applicants note that a physical mixture of two physically distinct types of particles, one type of particle comprising the agent, and a second type of particle comprising the polysaccharide, would NOT be intimately mixed "on a molecular level," even for very small particle sizes, because the individual molecules of the agent and the polysaccharide would not be intimately mixed within a common solid phase particle. In contrast, solid compositions such as those prepared by processes similar to those of claim 33 (such as freeze drying) would tend to produce non-crystaline phases wherein the individual molecules of the agent would be intimately mixed with individual molecules of the polysaccharide, within the solid phase.

Applicants submit that the claim amendments to claim 32, and the above comments, adequately address the Examiner's concerns and overcome the rejection.

REJECTIONS OF CLAIM 78 UNDER 35 USC 112, 2ND PARAGRAPH

The Office Action rejected claim 78, alleging "because the specification, while being enabling for a vaccine comprising a pectic substance as set forth in claim 53, wherein the vaccine increases the amount of IgA specific for the vaccine antigen in lung washing of an animal by about 10% after nasal administration, does not reasonably provide enablement for increasing amounts of IgA specific for any other antigen, or for increasing levels of IgA in lung washings when the composition is not delivered to the lung."

Applicants have amended and/or clarified claim 78, and claim 77 upon which it depends. These claims now recite that the vaccine is administered to the nasal mucosa of the animals, and that the IgA levels measured in the property test recited in claim 77 are antigen specific IgA levels, as was reported in Example 29, and/or Figure 11, wherein vaccines comprising diphtheria or influenza antigens were administered nasally to mice, then the lung washings of the mice were assayed for antigen specific IgA, with increases in the antigen titers far in excess of the 10% minimum recited in claim 78. The amended claims should not be interpreted to relate to non-antigen specific IgA levels, thereby addressing the Examiner's concerns regarding the lack of enablement of embodiments relating to non-antigen specific IgA levels. As to the Examiner's concerns as to how IgA levels measured in lung washings result from nasal administration, Applicants decline to comment on the specifics of scientific theory or mechanism, but note that Example 29 and/or Figure 11 make it clear that such results are actually observed with two different antigens, and accordingly the Examiner's grounds of rejection have been addressed and overcome.

REJECTIONS FOR ANTICIPATION AND/OR OBVIOUSNESS OVER THE PRIOR ART

Applicants appreciate the indication of the Examiner on page 13 of the Office Action that "Claims 4, 40, 55, 63, 65-67, and 101 are objected to as depending from a rejected claim but would be allowable if re-written in independent form incorporating all of the limitations of the claims from which they depend."

The original independent claims were rejected in the Office Action over various cited pieces of prior art. In the interests of facilitating prosecution to provide rapid allowance, and without conceding the validity or effect of the Examiner's rejections over the cited prior art, Applicants have amended each of the independent claims to incorporate all the limitations of allowable claim 5, which now all recite that the compositions are in the form of a powder, and that the powder comprises a plurality of microparticles and/or microspheres having a particle size suitable to permit the microparticles or microspheres to pass through a sieve having an opening size of about 250 μM in diameter. Applicants submit that in view of the Examiner's indication of allowable subject matter based on claim 5, and Applicants concurrence in that opinion, the claim amendments submitted herewith overcome all the rejections over the prior art cited in the Office Action, and that those rejections should be withdrawn.

CONCLUSION

In view of the claims amendments and arguments recited above, Applicants respectfully submit that all outstanding objections and rejections stated in the Office Action have been overcome and should be withdrawn. Accordingly, the application is believed to be in condition for allowance and Applicants respectfully request issuance of a Notice of Allowance.

Attached herewith is a Request for a Three Month Extension of Time, and a Credit Card Payment Form PTO-2038 authorizing payment in the amount of $690.00 representing $510.00 for the fee for a small entity under 37 C.F.R. § 1.(a)(2), and $180.00 for the fee under 37 C.F.R. § 1.17(p). This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this document and any documents referenced herein as being enclosed herein are being deposited with the United States Postal Service as first class mail in an envelope addressed to: MAIL STOP AMENDMENT, Commissioner for Patents, P. O. Box 1450, Alexandria, VA, 22313-,1450, on the date indicated below.

Mark A. Murphy, Ph.D. — Date: August 21, 2006